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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,195	08/31/2001	Catherine R. Condie	P-9632.00	4493

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EXAMINER	
MACHUGA, JOSEPH S	

ART UNIT	PAPER NUMBER
3762	8

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,195	CONDIE ET AL.	
	Examiner	Art Unit	
	Joseph S. Machuga	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-22, 24-42 and 44-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-22, 24-42 and 44-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Drawings

1. The proposed drawing corrections are acceptable.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 is dependant upon a cancelled claim making the claim indefinite. For the sake of expediting prosecution the claim will be considered to be dependent on claim 45.

Applicants arguments are considered moot in view of the new grounds of rejection. Applicant is invited to contact the examiner if it is believed it will expedite prosecution in this case.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2-4, 6-8,10-18, 20-26, 28-30, 32-40, 42, 45, 46, 51-54, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam (#5081987) in view of Jadvar et al (#5010888), the Atar et al publication and Kaufman et al #4933873.

6. Nigam discloses a pacemaker having internal read-write memory that can store up to 17 minutes of data for later analysis. The device also includes a telemetry circuit 34/35 which can transmit the data to a PC for analysis. The reference does not teach using this device to induce a stress test.

7. Jadvar et al teaches that it is old and well known to use an esophageal type cardiac pacing device to run a stress test. The reference notes (column 7 lines 30+) that this is particularly useful for patients who are unable to perform an adequate exercise stress test. The reference also teaches to look for changes in the ST segment in an ECG to diagnose myocardial ischemia (column 3 lines 14+.) The system would also include a start and stop command.

8. Atar et al also teaches that it is old and well known to esophageal type cardiac pacing device to induce a stress test. The reference disclose a common method of a running such a test, which includes starting at an initial heart rate, (for example 120bpm) and slowly increasing the rate until a rate determined by the formula of 0.85 (220-age) is reached. The data is recorded for signs of myocardial ischemia. The test is terminated in the presents of angina, extremes in blood pressure, etc. (column 3, 4th paragraph.)

9. Kaufman et al discloses a medical testing device. The equipment includes a programmable clock/calendar that records data on when the next test should be run.

10. Given these disclosures it would have been obvious to one of ordinary skill in the art to modify Nigam's programmable pacemaker to induce a stress test, record the raw data and transmit the results to a external PC given Jadvar et al's teaching that this is a known alternative to the traditional treadmill test that some patients cannot tolerate. To run the stress test in the generally accepted method taught by Atar et al would also have been obvious to one of ordinary skill in the art given that reference. To add a clock/calendar to the system to record and schedule the next test would have been obvious given Kaufman et al's teaching that this feature is old and well known in the art and aids the patient in scheduling a medical workup.

Regarding claim 6, 8, 28 and 51 : To abort the stress test in response to a sign of myocardial ischemia by sending a signal to the implant is considered obvious given Atar et al's teaching that the test should be aborted in response to dangerous situations (Column 3, 4th paragraph.)

Regarding claim 20, 42 and 57: To step down the stress test in increments from the maximum rate to the minimum rate is considered obvious given that's it's accepted practice to do this during exercising.

11. Claims 5, 9, 27, 31 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam in view of Jadvar et al, Atar et al and Kaufman et al #4933873 as applied to claims 2-4, 6-8,10-18, 20-26, 28-30, 32-40, 42, 45, 46, 51-54, 56 and 57 above and further in view of Infinger et al 5464432.

Infinger et al discloses a pacemaker. The device includes an RF transmitter/receiver for communicating through telemetry to an external programmer. This enables a cardiologist to program the device and read data stored in the memory.
The specific type of transmitter/receiver (35,41) in Nigam's device is not disclosed. However, given Infinger et al teaching it would have been obvious to use an RF transmitter/receiver in that device given that it is an acceptable and proven transmitter/receiver for pacemakers.

12. Claims 19, 41 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam in view of Jadvar et al, Atar et al and Kaufman et al #4933873 as applied to claims 2, 24 and 45 above, and further in view of Haefner et al 5662688.

13. Haefner et al discloses a pacemaker having both pacing and defibrillating electrodes. The device provides a pacing pulse to the heart in respond to the absents of a depolarizing signal sensed for the purpose of treating arrhythmia's.

14. Given this disclosure it would have been obvious to add multiple pacing electrodes to Nigam's pacemaker to treat arrhythmia's as taught by Haefner et al.

15. Claims 47, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam in view of Jadvar et al, Atar et al and Kaufman et al #4933873 as applied to claim 45 above, and further in view of DeGroot 5836975.

16. DeGroot teaches adding patient activator switches to a pacemaker to give the user more control over the therapy. Given this teaching it would have been obvious to

add controls to the device of the proposed combination to allow the patient to control when the text is be administered.

17. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam in view of Jadvar et al, Atar et al, Kaufman et al #4933873 and DeGroot as applied to claim 47 above, and further in view of Infinger et al 5464432.
Infinger et al discloses a pacemaker. The device includes an RF transmitter/receiver for communicating through telemetry to an external programmer. This enables a cardiologist to program the device and read data stored in the memory.
The specific type of transmitter/receiver (35,41) in Nigam's device is not specifically disclosed. However, given Infinger et al's teaching it would have been obvious to use an RF transmitter/receiver in that device given that it is an acceptable and proven transmitter/receiver for pacemakers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph S. Machuga
Examiner
Art Unit 3762

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ANGELA D. SYKES
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